BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

PRV

PATENT- OCH REGISTRERINGSVERKET
Patentavdelningen

#2

Intyg
Certificate

Härmed intygas att bifogade kopior överensstämmer med de handlingar som ursprungligen ingivits till Patent- och registreringsverket i nedannämnda ansökan.

This is to certify that the annexed is a true copy of the documents as originally filed with the Patent- and Registration Office in connection with the following patent application.

PATENT- OCH REGISTRERINGSVERKET • PATENT- AND REGISTRATION OFFICE

(71) *Sökande* *Siemens-Elema AB, Solna SE*
Applicant (s)

(21) *Patentansökningsnummer* *0004141-8*
Patent application number

(86) *Ingivningsdatum* *2000-11-13*
Date of filing

Stockholm, 2001-08-13

För Patent- och registreringsverket
For the Patent- and Registration Office

Kerstin Gerdén
Kerstin Gerdén

Avgift
Fee *170:-*

PATENT- OCH REGISTRERINGSVERKET
SWEDEN

Postadress/Adress
Box 5055
S-102 42 STOCKHOLM

Telefon/Phone
+46 8 782 25 00
Vx 08-782 25 00

Telex
17978
PATOREG S

Telefax
+46 8 666 02 86
08-666 02 86

Description

Method for adaptive triggering of breathing devices and a breathing device

The present invention relates to a method for adaptive triggering of breathing devices according to the preamble to claim 1.

The present invention also relates to a breathing device according to the preamble to claim 7.

"Triggering" as used in the present application relates to the activation of any respiration phase, i.e. both inspiration phases and expiration phases. This is a broader meaning than what is normally understood by the term (triggering is normally only related to the activation of inspiration phases).

"Breathing device" as used in the present application relates to all known devices providing a breathable gas to a subject. This includes inter alia ventilators, respirators, anaesthetic machines and resuscitation devices.

State of the art breathing devices comprise triggering functionality based on the gas parameters flow and pressure.

A flow triggering system is known from EP - A2 - 0 459 647, which discloses a breathing ventilator where a predetermined rate of flow of gas is delivered towards a patient. The changes in the rate of flow are measured and a breath support is triggered when the change in the rate of flow exceeds a threshold value (trigger level).

A pressure triggering system is known from US - 4,050,458. Here pressure is measured and is analysed in respect to change of sign of a differentiated pressure signal. When a

change occurs, an assisted inspiration phase can be started. In order to avoid self-triggering due to naturally occurring variations in pressure, the presence of a predetermined drop in pressure can be an additional requirement for triggering of the inspiration phase.

Although these systems normally operate satisfactorily, there will be a delay time from the actual onset of a spontaneous inhalation attempt (originating in the respiratory centre of the brain) until triggering actually occurs. This delay time may be more than 200 ms. Part of this is due to the transit time of the nerve signal and response time of respiratory muscles, which have to start working before a change in pressure and flow can occur. But main part of the delay is due to the fact that triggering levels are set high enough to avoid any risk of self-triggering (i.e. the device is triggered to start an inspiration phase when there is no attempt made by the patient). It thus takes time before the effects of an inhalation reach the trigger requirement and start an inspiration phase.

This delay time is also present for variants of the flow and pressure trigger systems, such as volume trigger systems.

One attempt to avoid or reduce part of the delay time is disclosed in US-5,373,842, where a pressure trigger system utilises flow measurements on a bias flow to change the required trigger pressure level.

Although being a more stable trigger system with shorter response time, some of the delay time due remain.

Other described trigger systems uses other parameters such as impedance across the chest as disclosed in EP-B-0324275, nerve signals as disclosed in WO-00/00245 and muscle (myoelectric) signals as disclosed in WO-99/43374.

The first of these essentially have the same delay times as the flow/pressure related triggering parameters, since the impedance will not change until the lungs start changing due to muscle activity. Here, also, thresholds must be set to avoid self-triggering from other impedance sources.

The latter two have less delay, but are not ideal in all situations. Muscle detection, for instance, normally relates to myoelectrical signals in the diaphragm. As the document WO-99/43374 states, however, inhalations can start with other muscle groups. Measuring activity in all muscles related to respiration is not realistic. A solution to this problem is suggested in WO-99/43374, namely to have a separate flow or pressure trigger system operating in parallel and use a first come, first serve trigger operation. The delay time then remains for the flow/pressure trigger system (as well as for the muscle trigger).

It should also be noted that all systems triggering on excitable cell signals (nerves and muscles) are at risk of self-triggering unless a sufficiently high threshold for the triggering is set.

It is an object of the invention to achieve a method that improves the trigger methods described above.

It is a further object of the invention to achieve an breathing device having improved trigger features with respect to prior art triggering systems.

The first object is achieved in that the method set out in the introduction further comprises the method steps set out in the characterising part of claim 1.

Advantageous improvements and embodiments are apparent from the dependent claims to claim 1.

The inventive triggering method is essentially based on a state of the art triggering method utilising flow and/or pressure. The improvement lies in utilising excitable cell signals related to respiration for adapting the trigger requirements for the flow and/or pressure trigger method.

Excitable cells are divided into two groups in humans, nerve cells and muscle cells. Excitable cells related to respiration thus includes all nerves and muscles that take part in the respiratory actions.

One preferred way of adapting the trigger requirement in relation to flow and/or pressure trigger methods is to adjust the trigger level based on the excitable cell signal. Since the excitable cell signal is indicative of a commencing breath, the risk of self-triggering is in practice quite insignificant and the trigger level can therefore be set to much higher sensitivity than is possible in the "pure" flow and/or pressure trigger method.

Another preferred way of adapting the trigger requirement in relation to flow and/or pressure trigger methods is to adjust or create a window in which triggering is enabled. Here, a constant high sensitivity can be set for the trigger level. Only when the excitable cell signal so indicates, will a triggering be allowed to result in the onset of an inspiration (or expiration) phase.

A combination of these two is of course possible. For instance, a certain level in the excitable cell signal (which could be lower than the trigger threshold for known systems using only such signals for triggering) opens a window in which triggering can take place. As the signal level increases (as the case is if inspirations are concerned) the flow and/or pressure trigger level will be changed towards higher sensitivity. This would make it possible to use higher

sensitivity and yet minimise the risk of self-triggering due to signal disturbances.

It should here be noted that the prior art described is mainly concerned with triggering of inspiration phases. The method according to the invention is, however, not limited to inspiration phases. It is also usable for triggering expiration phases.

Expiration phase triggering is often based on measured maximum pressure/flow levels during the actual breath. Cycling off an inspiration could e.g. be made when measured flow drops below a certain percentage of maximum flow. In the method according to the invention, the percentage is one specific trigger requirement that can be adapted by utilising excitable cell signals.

In order to cover all patient types, the method could be further improved by applying further adaptation of the trigger requirement. One such further adaptation could be the use of the known flow dependent pressure trigger system disclosed in US-5,373,842, mentioned above.

A pressure dependent flow control would also be usable in addition to the adaptation made on basis of the excitable cell signal. In particular in view of the progress in development of extremely small and accurate pressure sensor, it has now become realisable to carry out pressure measurements within the lungs. Pressure measurements have thus become more reliable and usable.

The object regarding a breathing device is achieved in that the breathing device as set out in the introduction comprises the features set out in the characterising part of claim 7.

Advantageous improvements and embodiments are apparent from the dependent claims to claim 7.

Here, the breathing device could essentially be based on a state of the art device, which is then equipped or connected to an excitable cell signal detector for detecting excitable cell signals and further equipped or modified to carry out necessary calculations and adaptations corresponding to what has been disclosed above in relation to the method.

Essentially any known prior art device for detecting excitable cell signals (and extracting/converting/calculating respiratory related information therefrom) can be used in connection with the present inventive breathing device. In particular, any known device which uses excitable cell signal information for determining the onset of an inhalation can be used in connection with the present breathing device.

In the following, the method and breathing device according to the invention will be described in greater detail with reference to the Figures.

Brief description of the Figures:
FIG. 1 shows a first embodiment of a breathing device according to the invention;
FIG. 2 shows some of the elements of the breathing device according to the invention in more detail, and
FIG. 3 shows a second embodiment of a breathing device according to the invention

A breathing device 2 according to the invention is shown in FIG. 1. The breathing device 2 comprises in this embodiment a ventilator unit 6 connected to a patient 4 for delivering breathing gas to and removing breathing gas from the patient 4. Connection is in this case illustrated with a conventional tubing system 8 that can be connected to the patient via a tracheal tube, tracheotomy tube, face mask, etc.

Also connected to the patient 4 is an excitable cell signal detector, in this embodiment an oesophageal diaphragm electromyography detector 10. The excitable cell signal detector 10 is connected to the patient 4 via a catheter lead 12 and can communicate with the other parts of the breathing device via a communication link 14.

Another embodiment of the breathing device is shown in FIG. 3. Here the breathing device 16 includes all parts within the same casing. As with the breathing device 2, a conventional tubing system 6 connects the breathing device 16 to a patient 4.

In this second embodiment, the excitable cell signal detector is a phrenic efferent signal detector 16A. The phrenic efferent signal detector 16A is connected to the phrenic nerve on the patient 4 as indicated by the sensor line 18.

A more detailed embodiment of the breathing apparatus 2 (or 16) is shown in FIG. 2. Parts that are different between the embodiments 2 and 16 are shown in broken lines. The detailed embodiment in FIG. 2 only shows the elements that are relevant for the understanding of the operation of the breathing device in relation to the inventive method.

A pneumatic unit 20 regulates flow of gases to and from a patient (not shown) by means of a first valve unit 22A and a second valve unit 22B. Gases that are mixed to form a breathing gas are supplied via a first gas inlet 24A and a second gas inlet 24B. The gases are proportioned and mixed in the first valve unit 20A. Additional gas inlets can be included if further gases are to be mixed to the breathing gas. The breathing gas is supplied towards the patient via an inspiration tube 26 and from the patient via an expiration tube 28. The second valve unit 20B controls the outflow of breathing gas from the patient. An evacuation 30 dispels the gas.

The pneumatic unit 20 is controlled by a control unit 32. In this case, only the control unit's 32 operation in relation to triggering of respiration phases is discussed. Actual control of the pneumatic unit 20 to provide specific flows and pressures for supporting respiration is well known in prior art systems.

A sensor 34 measures pressure. The pressure signal is used by a first determination unit to determine a first respiration indication signal (e.g. pressure within the patient's lungs).

The first respiration indication signal is transferred to a comparator 38 for comparison with a trigger level. Basically, the comparator 38 can comprise circuitry (if made in hardware) or programming (if made in software) enabling it to compare the first respiration indication signal with an inspiration trigger level during expiration phases and an expiration trigger level during inspiration phases. As an example, the following relate to comparison with an inspiration trigger level.

In a prior art pressure trigger device, first respiration indication signal input into the comparator 38 would eventually reach the inspiration trigger level. Upon this, a signal generator 40 generates a trigger signal which is utilised by further control means 42 in the control unit 32 to start an inspiration phase by controlling the first valve unit 20A in the pneumatic unit 20.

In a similar manner could the second valve unit 20B be controlled to start an expiration phase.

According to the present invention, the triggering requirement is adapted by a second respiration indication signal, derived from detection of excitable cell signals.

Excitable cells, i.e. nerves or muscles, generate myoelectrical signals that can be detected and treated to derive information. In this instance, information related to respiration is of interest. It is thus signals from nerves and/or muscles involved in the respiration that should be detected.

The muscles involved in breathing are essentially the diaphragm and the scalene and external intercoastal muscles during inspiration and abdominal and internal intercoastal muscles during expiration. Of these, the diaphragm has the greatest importance and is therefore of greatest interest in detecting muscle signals. As disclosed in relation to the prior art discussion, it is known to detect diaphragm myoelectric signals by using an oesophageal catheter 44 on which a plurality of sensors 46 is applied to detect the signals. In a second determination unit 48 the signals can be filtered, amplified or treated in any known way to create a second respiration indication signal.

The second respiration indication signal is transferred to an adaptation unit 50. The adaptation unit 50 is connected to the comparator 38. Trigger levels (either set by an operator or fixed for different applications of the breathing device) are linked to the comparator 38 via the adaptation unit 50.

The adaptation unit 50 adapts the trigger requirement so as to achieve a more reliable, sensitive and stable triggering of respiration phases.

One way of adapting the trigger requirement is to adjust the trigger level in dependency of the second respiration indication signal. For inspiration triggering, this means (in the present embodiment) that the trigger level itself is brought closer to the actual pressure within the patient (the first respiration indication signal). The comparator 38 and signal generator 40 will therefore respond earlier to an

inspiration attempt from the patient than would be possible with prior art pressure trigger systems.

Another way of adapting the trigger requirement is to maintain a high sensitivity on the pressure trigger (i.e. trigger level being close actual pressure). To avoid self-triggering, the adaptation resides in inhibiting triggering as long as the second respiration indication signal is too low. As the second respiration indication signal reaches a certain level, triggering on pressure is enabled. With this approach, it becomes unnecessary for the operator to set trigger requirements.

A third way of adapting the trigger requirement is to combine the two previous. In short, triggering could be enabled at a first level of the second respiration indication signal and the trigger level could then be changed towards the value of first respiration indication signal.

The same is possible in relation to nerve signals. The phrenic nerve is one example of a nerve involved in respiration. The signals along this nerve can be detected by a sensor 54 (indicated in broken lines). Signal treatment differs somewhat from what is done with muscle signals, but there are known ways of extracting the information relevant to respiration from the nerve signal.

Another detailed embodiment of the breathing apparatus according to the invention is shown in FIG. 4. Elements that can be identical with elements in FIG. 2 have the same designation numbers.

In this embodiment, the pneumatic unit 56 includes a gas generator 58, such a compressor or a fan. The gas generator 58 takes in air via an inlet 60 and regulates a breathing gas flow into a breathing tube 62 according to control signals from a control unit 64. The breathing tube 62 can e.g. be

connected to a patient via a breathing mask with separate outlet for expired gas (not shown).

A pressure meter 34 measures pressure and transfers the pressure signal to the control unit 64. In the control unit a software program receives the pressure signal, processes it and compares it with a trigger level. Pressure is thus a first respiration indication signal. An oesophageal catheter 44 on which a plurality of sensors 46 is applied to detect the signals from the diaphragm after being introduced into the oesophagus. These signals are transferred to a determination unit 48 which determines a second respiration indication signal. The second respiration indication signal is transferred to an adaptation unit 70 to be used for adapting the trigger requirement. The adapting can be made in any of the ways discussed above in relation to FIG. 2. Trigger levels are input via numeral 52.

To further adapt the trigger requirement, a flow meter 66 is used to measure flow of gas in breathing tube 62. The flow signal is transferred to a determination unit for determining a third respiration indication signal. The third respiration indication signal is sent to the adaptation unit 70 for further or combined adaptation of the trigger requirement.

One way of making a combined adaptation, is to use the second respiration indication signal for enabling triggering and the third respiration indication signal for increasing sensitivity of the pressure trigger level.

Another way is to combine the second respiration indication signal and third respiration indication signal for altering the trigger level.

A combination of the two is of course also possible.

Combinations of the shown embodiments are possible. For instance, the pneumatic unit 20 in FIG. 2 can be replaced with the pneumatic unit 56 in FIG. 4 and vice versa (with appropriate changes in respective control unit 32, 64).

Further modifications can also be done by adding, combining or changing elements in the prior art with shown embodiments in this description. For example, the pneumatic unit can basically be any known pneumatic unit usable in a breathing device. The same is valid for the tubing system. For example, anaesthetic elements have not be shown in the embodiments, but can of course be used in the same manner.

It is not necessary to measure diaphragm myoelectrical signals via an oesophageal catheter. Other means of obtaining these signals can also be used. Similarly, myoelectrical signals from other respiratory muscles can be used in the same way.

The same is of course valid for the nerve signals, which need not be obtained from the phrenic nerve.

The basic inventive concept of the invention is the use of excitable cell signals to modify or adapt the trigger requirement for respiration phases, either as a method or implemented in a breathing device.

Claims

1. Method for adaptive triggering of respiratory phases in breathing devices, comprising the steps of

determining a first respiration indicator signal based on at least one of the parameters flow and pressure,

compare the respiration indicator signal with a trigger requirement and

generate a trigger signal when the respiration indicator signal fulfils the trigger requirement, characterised in that the method further comprises the steps of

measuring an excitable cell signal related to respiration,

determining a second respiration indicator signal based on the measured excitable cell signal and

adapting the trigger requirement in relation to the second respiration indicator signal.

2. Method according to claim 1, characterised in that the trigger requirement comprises a trigger sensitivity and that the adapting of the trigger requirement is made so a higher trigger sensitivity in relation to the first respiration indicator signal is achieved when the second respiration indicator signal indicates that a natural change of respiratory phase is commencing.

3. Method according to claim 1, characterised in that the trigger requirement comprises an enabling of triggering and that the adapting of the trigger requirement is made so a triggering can only occur when the second respiration indicator signal indicates that a natural change of respiratory phase is commencing.

4. Method according to any of claims 1 to 3, characterised in that the excitable cell signal is a nerve signal, preferably a phrenic efferent discharge.

5. Method according to any of the claim 1 to 4, characterised in that the excitable cell signal is a muscle signal, preferably a diaphragm electromyography signal.

6. Method according to any of the claims 1 to 5, characterised in that the determination of the first respiration indication signal is based on one of the parameters flow and pressure, and the method further comprises the steps of

determining a third respiration indicator signal based on the other of the parameters flow and pressure and

further adapting the trigger level in relation to the third respiration indicator signal.

7. Breathing device (2; 16) comprising a tubing system (8) connectable to a subject (4) , a pneumatic unit (20; 56) comprising means (22A, 22B; 58) for regulating breathing gas flows in the tubing system (8), a sensor system comprising at least one of a flow meter (66) and pressure meter (34) and a control unit (32; 64) for controlling the pneumatic unit (20; 56), the control unit (32; 64) comprises a first determination unit (36) adapted to determine a first respiration indication signal based on at least one parameter measured by the sensor system (34, 66), a comparator (38) to compare the first respiration indication signal with a trigger requirement and a signal generator (40) to generate a trigger signal for controlling triggering of respiratory phases based on the first respiration indication signal and the trigger requirement, characterised by an excitable cell signal detector (44, 46, 54) for detecting excitable cell signals related to respiration, a second determination unit (48) adapted to determine a second respiration indicator signal based on excitable cell signals detected by the excitable cell signal detector (44, 46, 54) and an adaptation unit (50; 70) adapted to adapt the trigger requirement based on the second respiration indicator signal.

8. Breathing device according to claim 7, characterised in that the adaptation unit (50; 70) is adapted to adapt the trigger requirement so a higher trigger sensitivity in relation to the first respiration indicator signal is achieved when the second respiration indicator signal indicates that a natural change of respiratory phase is commencing.

9. Breathing device according to claim 7 or 8, characterised in that the adaptation unit (50; 70) is adapted to adapt the trigger requirement so a triggering is enabled when the second respiration indicator signal indicates that a natural change of respiratory phase is commencing.

10. Breathing device according to any of claims 7 to 9, characterised in that the excitable cell signal detector comprises a nerve signal sensor (54), preferably a phrenic efferent signal sensor.

11. Breathing device according to any of claims 7 to 10, characterised in that the excitable cell signal detector comprises a muscle signal sensor (44, 46), preferably a diaphragm electromyography sensor.

12. Breathing device according to claim 11, characterised in that the diaphragm electromyography sensor comprises an oesophageal catheter (44) having an array of sensing electrodes (46).

Abstract

Method for adaptive triggering of breathing devices and a breathing device

A method for adaptive triggering of respiratory phases in breathing devices, comprising the steps of determining a first respiration indicator signal based on at least one of the parameters flow and pressure, compare the respiration indicator signal with a trigger requirement and generate a trigger signal when the respiration indicator signal fulfils the trigger requirement is described. In order to shorten response times to respiration changes without loosing stability, the method further comprises the steps of measuring an excitable cell signal related to respiration, determining a second respiration indicator signal based on the measured excitable cell signal and adapting the trigger requirement in relation to the second respiration indicator signal. A breathing device implementing the method is also disclosed.

Fig. 1

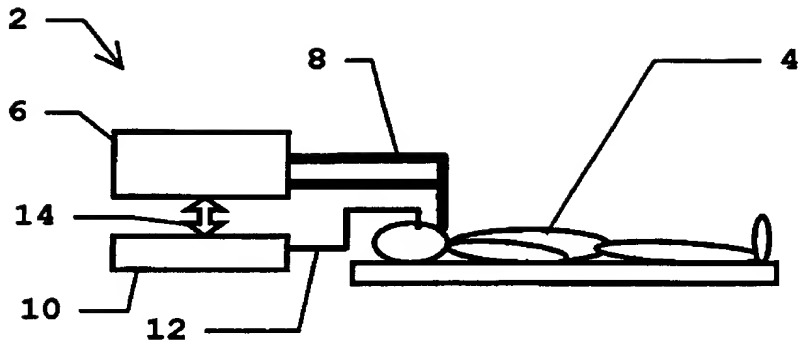
2
8
4
6
14
10
12

FIG. 1

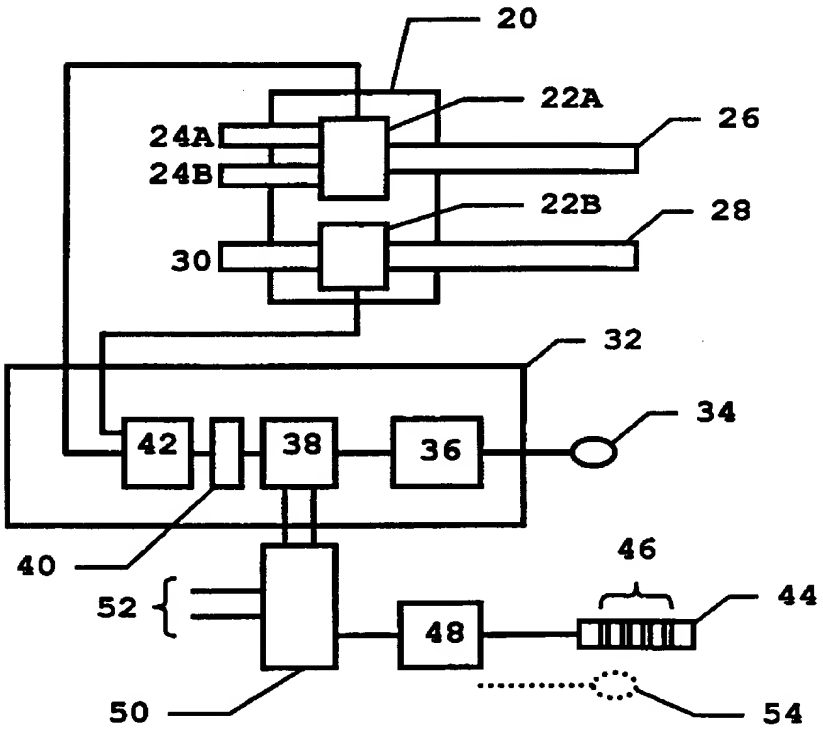
20
22A
26
24A
24B
22B
28
30
32
34
42
38
36
40
46
52
48
44
50
54

FIG. 2

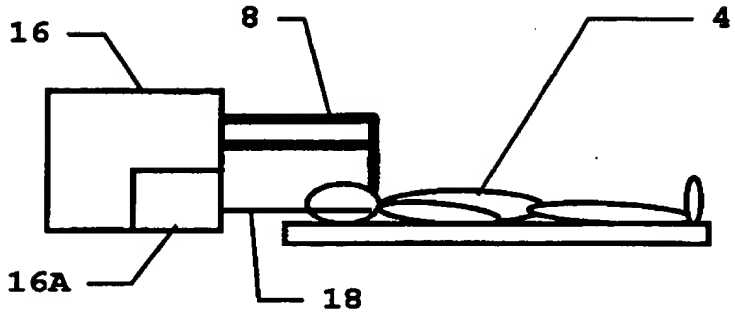

FIG. 3

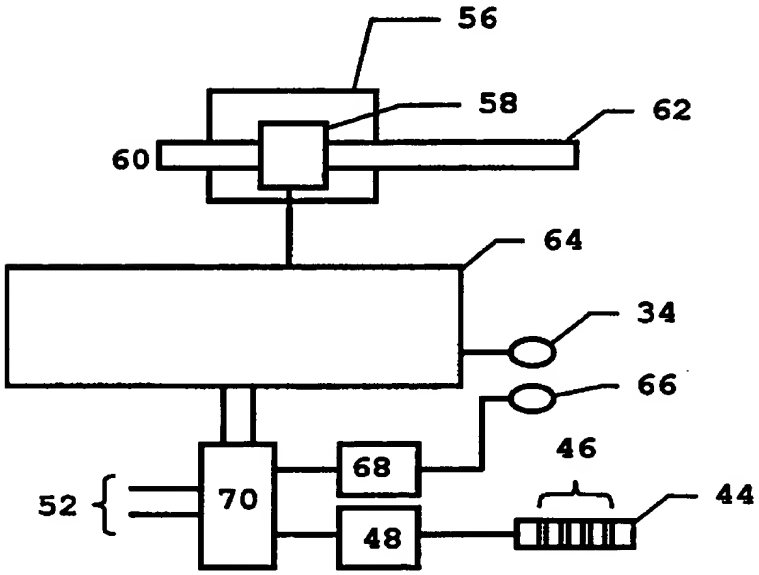

FIG. 4